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| 10/552,160 | 11/16/2005 | Lasse Petersen | 66386-371-7 | 9205 |
| 25769 7590 05/13/2009 DYKEMA GOSSETT PLLC FRANKLIN SQUARE, THIRD FLOOR WEST 1300 I STREET, NW WASHINGTON, DC 20005 | | | | |
| EXAMINER | | | | |
| OSTRUP, CLINTON T | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/552,160

Applicant(s)

PETERSEN ET AL.

Examiner

CLINTON OSTRUP

Art Unit

3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26, 28 and 30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17, 28 and 30 is/are rejected.
- 7) ☒ Claim(s) 26 and 118 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/11/05 & 2/23/09 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. This Office Action is in response to the Amendment filed February 23, 2009. As directed by the amendment, claims 1-26, 28 and 30 have been amended. Claims 27 and 29 are cancelled. Thus, claims 1-26, 28 and 30 are pending in this application.

Claim Objections

2. Claims 18-26 are objected to because of the following informalities: The status identifier of claim 18 describes the claim as "Previously Presented" and then the claim shows markings indicating the claim has been amended. For purposes of examination, the claim has been read with the marked up changes.

Any remaining claims are objected to as depending from an objected base claim.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-10 and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Collins (EP 1219316 A2) in view of Pagan (6,604,525).

Regarding claim 1, Collins discloses a laryngeal mask (see figure) comprising an airway tube (1) having a lumen (hole in tube); and a mask portion (2), said mask portion (3) comprising an inflatable cuff (21); and an intermediary portion (20) forming a transition from said airway tube (1) to said inflatable cuff (21), wherein the airway tube

(1) and the intermediary portion (20) are integrally molded, and the inflatable cuff (21) has a first peripheral edge integrally with said intermediary portion (where 25 forms the peripheral edge to where the cuff is attached) a second peripheral edge (where 26 forms the edge where the cuff is attached) connected to said intermediary portion by a joint (adhesive forming connection). Collins teaches all the limitations of instant claim 1 except the inflatable cuff with a first peripheral edge integrally molded with said intermediary portion. See: page 1, [0001]-[0012], figure and abstract.

Pagan teaches integrally forming a mount and a cuff member of a laryngeal mask. See: col. 1, line 35 - col. 3, line 47 and figures 1-9.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the laryngeal mask disclosed by Collins by integrally forming a cuff to a mount, as taught by Pagan to obtain a one piece, integrally formed laryngeal mask that eliminates the time consuming gluing of a cuff and the possibility of a faulty bonded cuff.

The combination of Collins with Pagan appears to meet all the structural limitations of the apparatus claimed. However, claim 1 is a Product by Process claim and "[T]he lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established. We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-

process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

Regarding claims 2-8, Collins discloses that the cuff is a thin flexible plastic material and that by molding the tube and mount together enables the wall thickness or shape to be varied, if desired, at different points along the tube. Thus, modifications of the tube thickness are clearly taught by the reference and the mere modification of a tube size is within the skill of those in the art.

Regarding claim 9, the combined references teach a rigid tubing (10) in extension of the airway tube which is completely or partially enclosed by an outer jacket (12) configured as an integral part of the airway tube. See: Pagan, figure 1.

Regarding claim 10, Collins discloses a groove in the airway tube and since the combined references teach the rigid tube as an integral part of the airway tube, it would have been obvious to extend the groove through the entire length of the tube, thus, including the rigid tube. See: Collins, page 1, [0006] and figure 1.

Regarding claim 12, Collins teaches an integrally formed mount and tube made by injection molding. See: Collins, page 2 [0013].

Regarding claim 13, Pagan teaches surface formations in the form of ribs, or the like, as epiglottis glides. See: col. 2, lines 62-65. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified

shape of the epiglottis guides into more round bead like structures to perform the same function.

5. Claims 11 and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Collins (EP 1219316 A2) in view of Pagan (6,604,525), as applied to claim 1 above and further in view of Brain (2003/0037790).

The combined references teach all the limitations of claim 11 except the reinforcing ribs that are integral with the airway tube and axially parallel with the central axis of the airway tube.

Brain teaches a laryngeal mask with an airway tube that has reinforcing ribs that are integral with the airway tube and axially parallel with the central axis of the airway tube. See: page 10, [0156] and figures 10B, 10C, 10E, 37D, 48B, 48D, and 49B.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the airway way tube disclosed by the combined references by adding reinforcing ribs as taught by Brain to obtain an airway tube with a better fit to the anatomical airway than cylindrical tubes.

Regarding claims 14-15, Brain teaches a mask portion with two additional inflatable bellows on the top face of the mask. See: Brain, page 18, [0211]-0213] and figures 28-29.

Regarding claim 16, it is common knowledge in the art to apply a water soluble lubricant to an object prior to inserting it into a patient's orifice. Water soluble lubricants allows for easier, less intrusive insertion of objects into patient's orifices and it would have been obvious at the time the invention was made to one having ordinary skill in the

art to apply a lubricant prior to a laryngeal mask prior to inserting it into a patient's airway.

Regarding claim 17, Brain teaches a reinforced transition face comprising reinforcing ribs. See: figures 10F, 10G, 48 D, and 49B.

6. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable Brain (4,241,956) in view of Brain (2003/0037790) and further in view of Cook (6,422,239).

Brain '956 discloses a laryngeal mask (figures 10-12) comprising at least one airway tube (11) and a mask portion (10), which mask portion (10) comprises a top face (13) and a bottom face (opposite from top face), said bottom face comprising a lumen (14) that communicates with the tube (11) interior, and said top face (13) comprising a closed transition face, said mask portion (10) being at least on the bottom face in the periphery delimited by an inflatable cuff (18), wherein the cuff (18) of the mask portion comprises inflatable means 21 for abutment against a wall of a pharynx opposite a laryngeal opening for providing a tight connection of the mask portion and the laryngeal opening; and passages are formed between these abutment means and the top face of the mask portion. See: col. 8, line 28 – col. 10, line 42 and figures 10-12.

However, Brain '956 lacks the at least two inflatable bellows that are arranged on a top face of the inflatable cuff and are symmetrical about a longitudinal axis of the cuff, as claimed.

Brain '790 teaches at least two inflatable bellows that are arranged on a top face of a mask and are symmetrical about a longitudinal axis of the cuff. See: page 18, [0211]-[0213] and figures 28-29.

Cook teaches bellows (44) on a top face of the cuff. See: col. 5, line 54 - col. 6, line 12 and figures 5-6.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the inflation bellow on the top of the laryngeal mask disclosed by Brain '956 by using two symmetrical inflatable bellows as taught by Brain '790 and arranged the bellows directly on the cuff, as taught by Cook in order to form a laryngeal mask with bellows provide raised runners that help guide the placement of the inflatable cuff during insertion of the laryngeal mask and provides a cushioned reference of the mask to the back wall of the patient's pharynx.

7. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Collins (EP 1219316 A2) in view of Pagan (6,604,525), as applied to claim 1 above and further in view of Cook (6,422,239).

The combined references teach all the limitations of claim 30, except the cuff with reinforced sections foremost on a top face of the cuff.

Cook teaches a laryngeal mask with a cuff that has reinforced sections on the top face of the cuff. See: col. 5, line 54 – col. 6, line 12 and figure 4.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the laryngeal mask disclosed by the combined references by using raised runners as taught by Cook to form a cuff that help guide the laryngeal mask and help prevent lateral movement once the tube laryngeal mask is positioned in the body.

Response to Arguments

8. Applicant's arguments filed August 12, 2008 have been fully considered but they are not persuasive.
9. Applicant's argument to the rejection of claims 1-10 and 12-13, under 35 U.S.C. 103(a) as being unpatentable over Collins (EP 1219316 A2) in view of Pagan (6,604,525), has not been found convincing.
10. Applicant argues that the combination of Collins and Pagan will result in a mask where the airway tube and the mask portion are injection moulded first mould, where after the walls of the inflatable cuff portion are blow moulded.

However, the device taught by the combination of Collins and Pagan appears to meet all the structural limitations of the apparatus claimed. However, claim 1 is a Product by Process claim and "[T]he lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established. We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

Therefore, absent a clear showing that the apparatus of the combined references results in a structurally different apparatus from the apparatus claimed, the examiner considers the claimed apparatus to be an obvious variation of the apparatus taught by the combined references, particularly given how well known and widely used injection molding is in the art, as evidenced by applicants response filed February 23, 2009, at page 14, first full paragraph.

Allowable Subject Matter

11. Claims 18-26 are allowable over the prior art of record, but are objected to for the reasons set forth above.
12. As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON OSTRUP whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771